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10/018,595	06/05/2002	Dany Aubry	3795/OJ958	8359

7590

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Darby & Darby  
805 Third Avenue  
New York, NY 10022-7513

EXAMINER
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HAAS, WENDY C

ART UNIT	PAPER NUMBER
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1661

DATE MAILED: 09/21/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

Application No.

10/018,595

Applicant(s)

AUBRY ET AL.

Examiner

Wendy C Haas

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 11 March 2004.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1,2 and 6-37 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1,2 and 6-37 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 05 June 2002 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_\_.
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_.

### **DETAILED ACTION**

**The amendment filed March 11, 2004 has been entered. An Office Action on the case follows.**

#### ***Oath/Declaration***

The substitute declaration filed March 11, 2004 is acceptable, however, applicants should specifically authorize substitution of the prior declarations with the new declaration filed March 11, 2004. Applicant argued in the Remarks to the first Office action that the declaration filed 6/5/2002 was proper. This is not the case. A full declaration was not filed 6/5/2002, only the signature page was submitted. An oath or declaration cannot be amended. See MPEP §§ 602.01 and 602.02.

#### ***Claim Objections***

The objection to claim 5 is withdrawn because the claim has been canceled.

#### ***Claim Rejections - 35 USC § 112, first paragraph***

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

**Claims 1, 2, 6-11 and 13-17 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled**

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in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Specifically, the claim describes "a biomass immobilization matrix having a vertical configuration." There appears to be no support in the specification for a vertically-oriented immobilization matrix. The closest support available would be found on page 17, lines 21-27, which describes "[a]n immobilization matrix . . . wrapped in a vertical spiral configuration on a stainless steel matrix holding structure." This recitation appears to provide support for a vertical spiral structure.

A vertical spiral structure differs from a completely vertical structure by virtue of the substantially greater amount of horizontal and low-angle surface area present on the vertical spiral structure. Further, applicant's specification appears to provide support only for an immobilization matrix made of geotextile strips rather than a matrix constructed of any selected material.

***Claim Rejections - 35 USC § 112, second paragraph***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

**Claim 15 is rejected under 35 U.S.C. 112, second paragraph**, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Specifically, Claim 15 recites the limitation "The process of claim 14 wherein" in the preamble, however Claim 14 claims a culture system (i.e. an apparatus) and not a process. Accordingly, there is insufficient antecedent basis for this limitation in the claim.

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**Claims 32-37 are rejected under 35 U.S.C. 112, second paragraph**, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Specifically, Claim 32 recites the limitation "obtained from the process of claim 6" however Claim 6 claims a culture system (i.e. an apparatus) and not a process. Accordingly, there is insufficient antecedent basis for this limitation in the claim.

**Claims 33-37 are rejected under 35 U.S.C. 112, second paragraph**, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Specifically, Claims 33-37 recite the limitation "said mature somatic embryos" in however Claim 32 (the claim they depend from) claims a somatic embryo and not a **mature** somatic embryo. Accordingly, there is insufficient antecedent basis for this limitation in the claim.

**Claims 33 and 34 are rejected under 35 U.S.C. 112, second paragraph**, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Specifically, the term "morphologically normal" in claims 33 and 34 is a relative term which renders the claims indefinite. The term "morphologically normal" is not defined by the claim, the specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention. Clarification is needed.

***Claim Rejections - 35 USC § 102***

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

**Claims 1, 2, 6-10 and 13-17 are rejected under 35 U.S.C. 102(b)** as being anticipated by Weathers et al. ('464).

Weathers et al. ('464) teach an apparatus comprising a closed vessel [FIGs. 1-5], a biomass immobilization matrix positioned in the closed vessel with a vertical configuration [FIG. 4, number 301], a pump that enables adjustment of a level of liquid medium contained in a the closed vessel [Col. 4, lines 11-16], spraying equipment for spraying medium onto the biomass immobilization matrix [Col. 4, lines 15-16 and FIG. 1, number 32] and gas control equipment for controlling the concentration of oxygen in the gas phase of the closed vessel [Col. 4, lines 15-29]. The apparatus also comprises means for periodical nutrient refreshment or replacement [see FIG. 1, numbers 20, 38 and 40]. Weathers et al. also teach a sterilizable nylon / polypropylene immobilization matrix [Col. 4, lines 63-65].

The immobilization matrix illustrated in FIG. 4, number 301 has both vertical and horizontal components, which meets applicants claim of "comprising". Weathers et al ('464) do not disclose use of the culture system with specific conifer embryos or specific oxygen concentrations. However, as noted in section 2114 of the MPEP, "A claim containing a 'recitation with respect to the manner in which a claimed apparatus is intended to be employed does not differentiate the claimed apparatus from a prior art apparatus' if the prior art apparatus

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teaches all the structural limitations of the claim. Ex parte Masham, 2 USPQ2d 1647 (Bd. Pat. App. & Inter. 1987). Accordingly, claims 13-17 are also anticipated by Weathers et al. ('464).

***Claim Rejections - 35 USC §§ 102/103***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

**Claims 32-37 are rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Aitken-Christie et al. (WO 96/37096).**

Aitken-Christie et al. teach a culture of conifer somatic embryos.

Claims 32-37 are product-by-process claims. As set forth in section 2113 of the MPEP, the use of 35 U.S.C. 102/103 rejections in product-by-process claims has been approved by the courts:

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“[E]ven though product-by process claims are limited by and defined by the process, determination of patentability is based on the product itself. The patentability of a product does not depend on its method of production. If the product in the product-by-process claim is the same as or obvious from a product of the prior art, the claim is unpatentable even though the prior product was made by a different process.” In re Thorpe, 777 F.2d 695, 698, 227 USPQ 964, 966 (Fed. Cir. 1985) (citations omitted)

In the present claims, the product taught in Atiken-Christie et al., a culture of conifer somatic embryos is the same as the product claimed.

***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

**Claim 11 is rejected under 35 U.S.C. 103(a)** as being anticipated by Weathers et al. ('464) in view of Weathers et al. ('928).

The teachings of Weathers et al. ('464) are set forth above.

Weathers et al. ('464) do not teach a specific volume for the culture system container.

Weathers et al. ('928) teach a similar apparatus to the apparatus disclosed in Weathers et al. ('464) with a two liter culture chamber [Col. 14, line 22].

It would have been obvious to a person of ordinary skill in the art at the time the invention was made to modify the apparatus of Weathers et al. ('464) to have a two liter culture chamber.



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One would be motivated to do this because the use of a two liter culture chamber in Weathers et al. ('928) indicates this is the methods Weathers et al. were using as their preferred culture chamber size.

A person of ordinary skill in the art would have an expectation of success in using the preferred culture chamber size. As such, the invention as a whole was prima facie obvious to a person of ordinary skill in the art at the time the invention was made.

**Claim 12 is rejected under 35 U.S.C. 103(a)** as being anticipated by Weathers et al. ('464) in view of Archambault et al.

The teachings of Weathers et al. ('464) are set forth above.

Weathers et al. ('464) do not teach an immobilizing matrix with a vertical spiral configuration.

Archambault et al. teach a cell culture system with strips of a biomass immobilization matrix formed into a vertical spiral configuration [Page 294, second full paragraph].

It would have been obvious to a person of ordinary skill in the art at the time the invention was made to modify the apparatus of Weathers et al. ('464) to include a vertical spiral support structure.

One would be motivated to do the because Archambault et al. state that the vertical spiral configuration increases the "available cell-immobilizing area relative to the culture volume." This, in turn, would increase the number of cells cultivated.

A person of ordinary skill in the art would have an expectation of success in using the vertical spiral immobilization matrix because this increased available support surface area can be

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created in any environment capable of containing the support structure and the support structure's purpose is to facilitate cell production. As such, the invention as a whole was prima facie obvious to a person of ordinary skill in the art at the time the invention was made.

**Claims 18-31 are rejected under 35 U.S.C. 103(a)** as being anticipated by Weathers et al. ('928) in view of Aitken-Christie et al. ('001).

Weathers et al. ('928) teach an apparatus comprising a closed vessel; a biomass immobilization matrix positioned in the closed vessel; a liquid medium contained in the closed vessel with the level of same lower than the biomass immobilization matrix; spraying equipment for spraying medium onto the biomass immobilization matrix and gas control equipment for controlling the concentration of oxygen in the gas phase of the closed vessel.

Weathers et al. ('928) also teach a bioreactor culture process comprising the steps of:

- (1) installing a biomass immobilization matrix in a closed vessel;
- (2) sterilizing the biomass immobilization matrix and the closed vessel;
- (3) introducing a liquid culture medium in the closed vessel to immerse the biomass immobilization matrix;
- (4) adding a given volume of cultured cells in the liquid culture medium;
- (5) immobilizing the cultured cells onto the biomass immobilization matrix;
- (6) reducing the level of liquid culture medium to a level lower than the biomass immobilization matrix;
- (7) spraying liquid culture medium onto the biomass immobilization matrix;
- (8) controlling the concentration of oxygen in the gas phase of the closed vessel;

and (9) periodic refreshment/replacement of nutrients (see Column 3, lines 1-9).

Specifically, a culture chamber is supplied with an ultrasonic transducer to provide mist (Col. 12, lines 54-57) and a vent to control oxygen (Col. 13, line 34). The chamber has 3 levels of nylon mesh to hold the biomass being cultured. Medium can drain through this mesh (see Col. 14, lines 24-25 and Col. 4-5 lines 64-5.) The closed vessel culture chamber was sterilized before adding biomass (see Col. 13, lines 64-65 “sterile nutrient media from the sump at the bottom of the culture chamber,” “sterile and loaded with tissue” Col. 13, lines 21-22.) The ‘928 patent discloses flooding the culture chamber with liquid medium to “just above the tissue in the nylon matrix”, and then draining that liquid medium and culturing the tissue in the vessel with mist. (Col. 13, lines 35-48. The ‘928 patent also teaches nutrient refreshment or replacement (Col. 3, lines 1-9).

Weathers et al. (‘928) do not teach culture of conifer somatic embryos (they instead teach culture of conifer cells), harvesting/germinating the somatic embryos or use of a vertical or vertical spiral immobilization matrix.

Aitken-Christie et al. (‘001) teach a conifer somatic embryogenesis tissue culture process, including germination and harvesting of the somatic embryos produced (Col. 8, line 60).

A vertical or vertical spiral immobilization matrix is not materially different from the matrix disclosed in Weathers et al. (‘928) for purposes of the process absent some evidence that a vertical or vertical spiral matrix configuration would materially alter the effect of the process.

It would have been obvious to a person of ordinary skill in the art at the time the invention was made to use the process of Weathers et al. to produce conifer somatic embryos.

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One would be motivated to do this because Weathers et al. teach that their process allows for high-volume culture of conifer cells with limited loss of viability and is, in essence, a physical/mechanical process for increasing conifer cell production. Aitken-Christie disclose a chemical/media process of increasing conifer somatic embryo production that is not dependent on the physical mechanics of its environment and can be practiced with liquid media.

A person of ordinary skill in the art would have a reasonable expectation of success because combination of the two processes would be expected to further increase the efficiency of somatic embryo culture by increasing culture volume and decreasing loss of viability. As such, the invention was prima facie obvious to a person of ordinary skill in the art at the time it was made.

#### ***Response to Arguments***

Applicant's arguments with respect to Claims 1 and 2 have been considered but are moot in view of the new ground(s) of rejection.

With respect to applicant's comments on page 12 of the response, the Examiner notes that a prior art reference cited under 35 U.S.C. § 102(b) can anticipate the claimed invention whether or not it "teaches away" from same. "Teaching away" is an argument against obviousness.

With respect to Weathers '464, the patent does teach an initial flooding condition followed by lowering of the medium level with respect to the matrix. Applicant's argument that the comment in Weathers '464 noting that "it is of paramount importance ... that the cells are not sprayed with nutrient," does not teach away from the claimed invention. First, as noted by applicant, the claimed invention teaches spraying of the medium rather than the cells. Second,

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Fig. 1b illustrates that the sprayer is located in a position where the immobilization matrix could be sprayed without spraying the cells and the nutrients could then be dispersed to the cells by capillary action. Finally, the nutrient mist is beneficial, not toxic, to the cells and the concern about spraying the cells is directed to cell wall destruction, separation of the cells from the matrix by shear force, etc. Accordingly, it is likely that the comment in Weathers '464 relied upon by applicant could more accurately be described as motivation for a vertical matrix configuration than as a "teaching away".

With respect to Weathers '928, the examiner does not believe that a comment noting that the process described can be used on agar gels as well as operated within a bioreactor apparatus teaches away from the instant claimed invention.

### ***Conclusion***

No claim is allowed.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37

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CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.


***Future Correspondence***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Wendy C. Haas whose telephone number is (571) 272-0976. The examiner can normally be reached on Monday through Friday 9:00 to 5:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Andrew Wang can be reached on (571) 272-0811. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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